

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “second outer surface” of claims 4,11, the “first outer surface is at least partially situated on a part which can be applied to the implant” of claims 6,7, and the “inner and outer parts” of the “upper/outer portion” of claim 8 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Implant With Porous Outer Layer Promoting Tissue Integration.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** [emphasis added] The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Examiner suggests replacing "comprises" with "includes".

### ***Claim Objections***

3. Claims 5, 7, 13 are objected to because of the following informalities:

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- Claim 5 recites "dental implant and the **the** first outer covers" which appears to mean --dental implant and the first outer **surface** covers-- [emphasis added]. Also, it is not clear what "1/3/" means.
- Claims 7, 13 recite "between about is 1.5-1.8 mm" which appears to mean --between about 1.5-1.8 mm--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 7, 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 7, 13 positively recite a part of the human body and dimensions thereof.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5, 8, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Caterini (WO0105325).

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8. Caterini shows a dental implant (2) comprising a body (2) that includes an upper implant part (at 13 in Fig. 2-3) comprising less than 1/3 of the implant covered by the first outer surface (13) comprising a porous outer layer (13) to promote integration between the outer surface and soft tissue. With respect to claim 8, the implant includes an upper/outer portion (upper portion of Fig. 2-3) with an inner part (interior of implant 2) and an outer part (false stub 3) that may be temporarily removed during fitting of the dental implant. With respect to claim 10, absorption at the mouth of the hole is limited due to the top portion of the dental implant not being comprised of the porous outer layer (Fig. 2-3).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caterini in view of Jansen et al. (2004/0241613).

Caterini discloses the device as previously described above, but fails to show the pores having mean diameters less than or equal to about 1 micrometer and the porous outer layer having a thickness of less than or equal to 5 micrometers.

Jansen teaches a coating for use with dental implants that preferably has pore diameters in the range of 0.1-25 micrometers and a layer thickness of 0.5-20

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micrometers ([0042]-[0044]). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Caterini's implant by substituting the porous outer layer of Jansen in order to provide advantageous properties for the attachment of cells.

11. Claims 4, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caterini in view of Hall et al. (2003/0157460).

Caterini discloses the device as previously described above, but fails to show a second outer surface being coarser than the first outer surface by 30% to 40%.

Hall teaches outwardly porous surfaces providing porosities of different degrees ([0004]). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Caterini's implant to include portions of different porosities of Hall in order to increase the surface areas for bone union. It would have been further obvious to one having ordinary skill in the art at the time of invention to have chosen portions that differ by 30% to 40% porosity from one another in order to accommodate different types of bone ([0004]) since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. MPEP 2144.05 II.

12. Claims 6-7, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caterini.

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Caterini discloses the device as previously described above, but fails to show the first outer surface partially situated on a part which can be applied to the implant or the first outer surface being at least partially situated on a part which is integrally formed with the rest of the implant, and the implant configured so that the height of the soft tissue above the bone margin is between about 1.2-2.0 mm or 1.5-1.8 mm. It would have been obvious to one having ordinary skill in the art at the time of invention to have made the first outer surface's part separable from the rest of the implant, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. It would have been likely obvious to make a separable part integral. See MPEP 2144.04 V. It would have been further obvious to one having ordinary skill at the time of invention to have modified the height of soft tissue above the bone margin to between 1.5-1.8 mm in order to avoid exposure of the underlying implant surface since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. MPEP 2144.05 II.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caterini in view of Petersson et al. (2006/0154206).

Caterini discloses the device as previously described above, but fails to show the porous outer layer being based on anodic oxidation.

Petersson teaches applying an oxide layer to a titanium implant using anodic oxidation ([0014]). Therefore, it would have been obvious to one having ordinary skill in

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the art at the time of invention to modify Caterini's outer porous layer to be based on the anodic oxidation of Petersson in order to achieve thin layers of oxide coating.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew M. Nelson whose telephone number is (571) 270-5898. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MMN/

/Cris L. Rodriguez/

Supervisory Patent Examiner, Art Unit 3732